IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

	)	**REDACTED**
IN RE: '318 PATENT INFRINGEMENT	)	**PUBLIC VERSION**
LITIGATION	)	
	)	Civil Action No. 05-356-SLR
	)	(consolidated)

PLAINTIFFS' MOTION TO
EXCLUDE MICHAEL RAINER FROM TRIAL

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Dated: March 9, 2007

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	))	Civil Action No. 05-356-SLR (consolidated)

PLAINTIFFS' MOTION TO
EXCLUDE MICHAEL RAINER FROM TRIAL

By this Motion, Plaintiffs seek to preclude use by Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, "Barr") at trial of a witness that was never disclosed during discovery (or many months thereafter). In so doing, Plaintiffs are mindful of the fact that the Court typically does not entertain motions *in limine* and prefers to address significant evidentiary matters at the pretrial conference. We respectfully request the Court's indulgence in bringing this short speaking Motion, however, because, given its nature, we are concerned that Barr would complain about any delay in our bringing this to the Court's attention. Accordingly, out of an abundance of caution we have filed this Motion promptly upon learning of Barr's intentions regarding this previously undisclosed witness so that the Court may consider the issue now.

Fact discovery closed in this case on July 7, 2006. **Eight months after the close of fact discovery**, Barr disclosed Dr. Michael Rainer as a potential "rebuttal" witness — *for the first time* — on March 2, 2007. Rainer, an employee of the Austrian company Waldheim Pharmazeutika GmbH ("Waldheim"), is a foreign non-party who has never previously been identified as a source of discoverable information, much less as a potential trial witness. Barr was required by Federal Rules of Civil Procedure 26(a)(1)(A), 26(e)(1) and 26(e)(2) to disclose

Rainer as a potential trial witness as soon as it learned that he was "likely to have discoverable information that [Barr] may use to support its claims or defenses." Barr failed to comply with the Rules — and accordingly, Rainer should be excluded as a witness at trial.

Barr's violation of the Rules and belated disclosure of Rainer have deprived Plaintiffs of the opportunity to take meaningful discovery on alleged invalidity issues raised by this witness and, given the trial schedule, have incurably prejudiced Plaintiffs. Because of the severe prejudice that would be caused by the admission of Rainer's testimony, Plaintiffs respectfully ask the Court to exclude Rainer's testimony from trial.[1] *See Praxair, Inc. v. ATMI, Inc.*, 445 F. Supp. 2d 460, 469 (D. Del. 2006) (excluding prior art reference from trial that was not previously disclosed in the litigation — even though it was referenced in the prosecution file history — where the non-disclosing party was deprived of adequate time for discovery and expert analysis); *Cufee v. Dover Wipes Co.*, 334 F. Supp. 2d 565 (D. Del. 2004) (striking expert opinion that was disclosed five months before trial but was untimely). *See also Nicholas v. Penn. State University*, 227 F.3d 133, 148 (3d Cir. 2000) (Alito, J. upholding exclusion of evidence because its disclosure was delayed from November 1997 to May 1998 and the relevant documents were only produced in June 1998, one month before the relevant hearing); *Muldrow v. Brooks*, 34 Fed. Appx. 854 (3d Cir. Apr. 29, 2002) (unpublished) (upholding exclusion of trial witness not disclosed in Rule 26 disclosures even though referenced during deposition).

Over the nearly two-year history of this litigation, Barr has had innumerable opportunities to properly disclose Rainer as a potential fact witness. At each opportunity, Barr opted for silence over disclosure, as demonstrated by the following chronology:

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[1] Plaintiffs' counsel has conferred with Barr's counsel to try to resolve this dispute, but Barr has been unwilling to withdraw Rainer as a witness.

- **June 10, 2005** — Plaintiffs filed suit against Barr.

- **June 30, 2005 —** Barr filed its Answer, Affirmative Defenses and Counterclaim.

- **October 10, 2005 —** Barr served its Rule 26(a)(1) Initial Disclosures; ***no mention of Rainer*** was made in the Initial Disclosures. *See* Exhibit A.

- **October 11, 2005 —** Barr responded to Plaintiffs' first set of interrogatories, including an interrogatory requesting identification of "each witness [Barr] intend[s] to call at trial"; ***no mention of Rainer*** was made in this response. *See* Exhibit B.

- **December 20, 2005 —** At Defendants' request, Judge Jordan moved the trial date up from October 2007 to June 2007. In moving the trial date to June of 2007, Judge Jordan instructed the parties, "[I]f you think you are going to need third-party discovery overseas – ***this goes for plaintiff and any of the defendants*** – don't wait to do it . . . I urge you to move forward on that as soon as possible." *See* Exhibit C (12/20/05 Hearing Transcript, 10:24 - 11:4) (emphasis added).

- **January 30, 2006** — Plaintiffs' eighth production of documents included documents purportedly authored by Rainer. ***Barr was thus provided documents referring to Rainer well over a year ago.***

- **February 6, 2006 —** Barr's counsel referred to Rainer and Waldheim in questioning John Richards, Esq. (the Ladas & Parry 30(b)(6) designee). *See* Exhibit D (2/06/06 Ladas & Parry 30(b)(6) Dep. Tr. at 21:20 - 23:17).

- **February 8, 2006** — Bonnie Davis referred to Rainer in her deposition testimony. *See* Exhibit E (2/08/06 B. Davis Dep. Tr. at 191:25 - 192:22).

- **February 9, 2006** — Defendants engaged in extensive questioning of Bonnie Davis regarding Rainer and Waldheim. *See* Exhibit F (2/09/06 B. Davis Dep. Tr. at 317:15 - 367:25).

- **April 13, 2006 —** Barr supplemented its response to Plaintiffs' Interrogatory Number 2 (which sought to discover the factual bases for Barr's contentions of invalidity); ***no mention of Rainer*** was made in this supplemental response. *See* Exhibit G.

- **May 17, 2006** — Barr responded to Plaintiffs' Second Set of Interrogatories (which include Interrogatory Number 4 which asks about the factual bases for Barr's contentions of patent invalidity under 35 U.S.C. §§ 101, 102, 103, 112 or 116); ***no mention of Rainer*** was made in this response. *See* Exhibit H.

- **July 7, 2006** — Fact discovery closed; by this date, Barr had made ***no supplementation to Initial Rule 26 disclosures and no supplementation to answers to Interrogatory Nos. 2 or 4 to disclose Rainer*** as a witness. Barr pursued no foreign third-party discovery related to Rainer.

- **October 27, 2006** — Close of expert discovery; ***no mention of Rainer as a potential trial witness was made*** by Barr.

It is beyond dispute that Barr did not abide by the applicable rules to timely disclose Rainer as a knowledgeable fact witness or possible trial witness. For example, when specifically asked for its invalidity contentions with regards to the patent-in-suit, Barr did not identify Rainer or any of the issues that his testimony might raise in response to Plaintiffs' interrogatories. Specifically, on April 17, 2006 Plaintiffs asked:

> **Interrogatory No. 4**: If [Barr] believes that any asserted claim of the '318 patent is invalid for failure to satisfy one or more of sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code, explain the basis for such belief according to its proof elements . . . and identify all documents that relate to [Barr's/Alphapharm's] invalidity contentions as well as the *five (5) most knowledgeable persons* concerning such invalidity contentions. (emphasis added).

Barr's ten-page response to Interrogatory No. 4, served on May 17, 2006, not only fails to identify Rainer, but also appears not to disclose any theory of invalidity that his testimony is likely to support. *See* Exhibit H, Barr's Answer to Interrog. No. 4.

Under Rule 37(c)(1), Rainer's surprise testimony should be excluded from trial. The Court of Appeals for the Third Circuit identifies four factors that courts should evaluate in determining whether witness preclusion is warranted: (1) the prejudice or surprise arising from untimely evidence; (2) the ability to cure the prejudice; (3) the extent to which allowing violation of the scheduling order would disrupt the trial process; and (4) the proponent's bad faith or willfulness in failing to comply with the court's order. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791 (3d Cir. 1994); *Praxair*, 445 F. Supp. 2d at 469. All of these factors support the exclusion of Rainer's testimony.

(1) Prejudice and surprise to Plaintiffs. Because Barr never identified Rainer as a possible trial witness or person with relevant knowledge — despite its obligation to do so under the Rules — Plaintiffs had no reason to pursue foreign third-party discovery related to

him. Rainer's late appearance in the case reflects an attempt by Barr to introduce on the eve of trial an entirely new factual basis for its invalidity contentions, undisclosed in its Rule 26(a) Initial Disclosures and responses to Plaintiffs' Interrogatories.[2] In so doing, Barr would effectively deprive Plaintiffs of an opportunity to properly discover Rainer's factual contentions and the bases for those contentions.[3]

(2), (3) Inability to cure prejudice/disruption of trial process. Plaintiffs simply do not have time to conduct adequate discovery on this new issue. Although Barr still has not disclosed an address or contact information for Rainer as required by Rule 26(a)(1)(A), Plaintiffs have reason to believe that he resides in Germany and is affiliated with German and Austrian entities, raising the need for foreign discovery through the Hague Convention process. Even in the highly unlikely event that the Hague Convention process could be completed in the short time remaining before trial, Plaintiffs will be fully immersed in trial preparation and will thus have no opportunity to adequately prepare for a deposition of Rainer or of the institutions with which he has been affiliated. Barr's eleventh-hour injection of Rainer into this case would also deprive Plaintiffs of the right to take appropriate discovery in connection with Rainer's proposed testimony — i.e., to seek appropriate discovery of Rainer's documents, to seek further discovery prompted by Rainer's testimony, to identify rebuttal witnesses, to seek the production

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[2] While nowhere contained in its interrogatory answers or Rule 26(a) Initial Disclosures (or any supplementation), just a few days preceding this filing Barr has urged that Rainer "had the idea to use galantamine to treat Alzheimer's disease as early as October 1985, months before Dr. Bonnie Davis filed her patent application." *See* Exhibit I, Ulrich March 2, 2007 letter to Calia. Barr thus appears to believe that Rainer is an important witness as to alleged invalidity — *despite* his non-disclosure during discovery.

[3] That one of Barr's two medical experts made passing reference to Waldheim during a deposition is irrelevant, as those statements were also made well after the close of fact discovery and cannot cure the deficiencies in Barr's Rule 26(a) Initial Disclosures or its responses to Plaintiffs' interrogatories.

of related third-party documents, or to develop expert opinions responding to Rainer's contentions. Given the lengthy Hague Convention process required to compel additional foreign discovery and the time needed for expert review, it is simply impossible to reconcile Rainer's potential May 2007 trial testimony with a fair opportunity for Plaintiffs to conduct adequate discovery. Plaintiffs have been assiduously preparing for a May trial and should not, as trial is about to begin, have their preparation disrupted because of Barr's failure to timely disclose Rainer as required by Rules 26(a)(1)(A), 26(e)(1) and 26(e)(2).

(4) Bad faith or willfulness. It is beyond dispute that Barr had documents that disclosed Rainer and Waldheim as early as January 30, 2006. It is also indisputable that Barr made repeated reference to both Rainer and Waldheim in Plaintiffs' depositions in February of 2006. *See, e.g.*, Exhibit D (2/06/06 Ladas & Parry 30(b)(6) Dep. Tr. at 21:20 - 23:17); Ex. E (2/08/06 B. Davis Dep. Tr. at 191:25 - 192:22); Ex. F (2/09/06 B. Davis Dep. Tr. at 317:15 - 367:25). In connection with a Rule 30(b)(6) deposition of Plaintiff Synaptech, Barr's counsel even claimed in an August 2006 hearing before Judge Jordan that "Waldheim is at the center of this case" — but there, again, failed to properly identify Waldheim as an area of deposition inquiry under the Rules, leading Judge Jordan to prohibit Barr from pursuing Waldheim as a deposition topic and to note that Barr was "off the reservation" with its Waldheim questioning. *See* Exhibit J (8/30/06 B. Davis Dep. at 89:3 - 92:7; 99:17-18). Clearly, Barr was aware that Rainer may have had discoverable information well before the close of fact discovery and yet failed to comply with the Rules by so disclosing him.

Indeed, the chronology in this case demonstrates that despite many opportunities, Barr did not, as required by the Rules, reveal the prospect of Rainer's trial testimony until well after the close of discovery. In fact, Barr did not reveal Rainer until Plaintiffs could no longer

respond — effectively sandbagging Plaintiffs and leaving them without an opportunity to conduct discovery related to Rainer/Waldheim and the entirely new issues his testimony might raise.

Barr failed to comply with its obligations under the Rules to disclose "each individual likely to have discoverable information that the disclosing party may use to support is claims or defenses." Fed. R. Civ. P. 26(a)(1)(A). Indeed, the manifest prejudice caused by this sort of "trial by ambush" litigation strategy is exactly what the Federal Rules and this Court's Orders seek to avoid. Barr's clear violation of the spirit and the letter of the Federal Rules and of this Court's Orders should not be countenanced, and the Court should, as it has done in similar circumstances, exclude from trial any evidence related to Rainer and Waldheim. *See Praxair*, 445 F. Supp. 2d at 469; *Cufee*, 334 F. Supp. 2d at 572.

ASHBY & GEDDES

/s/ *Tiffany Geyer Lydon*

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Dated: March 9, 2007
178735.1

CERTIFICATION PURSUANT TO LOCAL RULE 7.1.1

I hereby certify that counsel for Plaintiffs has discussed the subject of the attached motion with counsel for Defendants, but that no agreement could be reached.

/s/ Tiffany Geyer Lydon

_____

Tiffany Geyer Lydon

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	Civil Action No. 05-356-SLR (consolidated)

ORDER

This _____ day of _____, 2007, Plaintiffs having moved to exclude Michael Rainer from trial, and the Court, after considering the motion, having concluded that good grounds exist for the requested relief, now therefore,

IT IS HEREBY ORDERED that Plaintiffs' motion is granted.

_____
Chief Judge

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., and SYNAPTECH, INC.,	
Plaintiffs/Counterclaim-Defendants,	C.A. No. 05-00381 (KAJ)
v.	**JURY TRIAL DEMANDED**
BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.,	
Defendants/Counterclaim-Plaintiffs.	

BARR LABORATORIES, INC.'S AND BARR PHARMACEUTICALS, INC.'S RULE 26(a)(1) INITIAL DISCLOSURES

Pursuant to Rule 26(a)(1) of the Federal Rules of Civil Procedure, Defendants-Counterclaim-Plaintiffs Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, "Barr"), without waiving any claim of privilege, work product protection, or other basis for non-disclosure, provide the following written statement of initial discovery disclosures. Barr reserves the right to supplement and/or amend these initial disclosures in accordance with the Federal Rules of Civil Procedure and the local rules of the Court and/or as investigation in this matter continues and new facts come to light.

Disclosures

A. Pursuant to Rule 26(a)(1)(A) of the Federal Rules of Civil Procedure, Barr identifies the following individuals or companies, with addresses and telephone numbers where known, who may have discoverable information that Barr may use to support its claims and defenses currently set forth in Barr's pleadings. The following list is not intended to be exhaustive. Barr's investigation continues. Barr will conduct additional searches should the

need for supplementary information arise and should a proper request be made in a timely manner. Barr reserves the right to amend and/or supplement its disclosures as the case progresses and discovery is taken.

Identity of Company and/or Individual	**Subject Matter**
Any individuals currently or formerly employed by : Janssen Pharmaceutica N.V. Turnhoutseweg 30, B-2340 Beerse, Belgium	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the sale of Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.
Any individuals currently or formerly employed by : Janssen, L.P. 1125 Trenton-Harbouton Road P.O. Box. 200 Titusville, NJ 08560	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the sale of Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.
Any individuals currently or formerly employed by : Synaptech, Inc. c/o Ladas & Parry 26 West 61st Street New York, NY 10023	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the sale of Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.

Identity of Company and/or Individual	Subject Matter
Bonnie Davis 17 Seacrest Drive Huntington, NY 11743	Knowledge concerning, among other things, the alleged conception and reduction to practice of the invention allegedly claimed in the '318 patent; the claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.
John Richards Ladas & Parry 26 West 61st Street New York, NY 10023	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.
Lester Horwitz Ladas & Parry 26 West 61st Street New York, NY 10023	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.
Joseph H. Handelman Ladas & Parry 26 West 61st Street New York, NY 10023	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation, and Janssen's anticipated defenses to Barr's counterclaims in this litigation.
Ladas & Parry 26 West 61st Street New York, NY 10023	Knowledge concerning, among other things, the alleged invention and claims of the '318 patent, the prosecution of the '318 patent, Janssen's galantamine hydrobromide products, the allegations asserted against Barr in the complaint filed by Janssen in this litigation,

Identity of Company and/or Individual	Subject Matter
	and Janssen's anticipated defenses to Barr's counterclaims in this litigation.

B. Pursuant to Rule 26(a)(1)(B) of the Federal Rules of Civil Procedure, Barr provides the following description by category and location of documents, data compilations, and tangible things that are in its possession, custody, or control that Barr may use to support its claims or defenses, unless solely for impeachment. By making these disclosures, Barr reserves the right to object to the admissibility, relevance, and the like of such documents and evidence. It is Barr's position that any documents produced before the entry of a Rule 26 Protective Order are to be treated in accordance with D. Del. Local Rule 26.1.

1. United States Patent No. 4,663,318;

2. Prosecution History of United States Patent No. 4,663,318;

3. Barr Laboratories, Inc.'s Abbreviated New Drug Application No. 76-605 filed by Barr Laboratories, Inc. with the FDA;

4. Rathmann, K.L. and Conner, C.S., "Alzheimer's Disease: Clinical Features, Pathogenesis, and Treatment," *Drug Intell. Clin. Pharm. 18*:684-91 (1984);

5. Cozanitis, D.A., "L'hydrobromide de galanthamine: un substitut du sulfate d'eserine (physostigmine) pour le traitement des effets cerebraux des substances anti-cholinergiques," *Nouv. Presse Med. 34*:4152 (1978); and

6. Any and all prior art or other documents identified by any Defendant in any of the related actions filed by Janssen in connection with galantamine hydrobromide.

Barr's counsel has a copy of the documents cited in categories (1) - (5) and has produced a copy of such documents to Janssen's counsel under separate cover on October 10, 2005. Barr notes that the documents in category 6 are publicly available. Barr reserves the right to supplement and/or amend these disclosures as necessary or appropriate in accordance with the

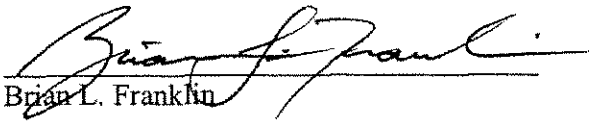
Federal Rules of Civil Procedure and the local rules of this Court and/or in response to specific discovery requests of Janssen.

C. Pursuant to Rule 26(a)(1)(C) of the Federal Rules of Civil Procedure, Barr discloses that it is seeking an award of attorneys' fees and costs. Barr will make available for inspection and copying, at the appropriate time, the documents and/or computations, together with supporting documents, concerning any claims for attorneys' fees under 35 U.S.C. 285, interest, and costs of this action. Barr reserves the right to seek additional damages from Janssen.

D. Pursuant to Rule 26(a)(1)(D) of the Federal Rules of Civil Procedure, Barr does not carry insurance coverage applicable to the claims raised in this lawsuit.

Date: October 10, 2005

BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.

By: 
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CERTIFICATE OF SERVICE

The undersigned attorney certifies that he caused a copy of the foregoing Rule 26(a)(1) Initial Disclosures of Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. to be served this 10th day of October, 2005, on the counsel of record by sending a copy by Federal Express to:

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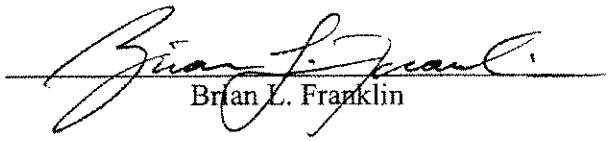

Brian L. Franklin

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., and SYNAPTECH, INC.,	
Plaintiffs/Counterclaim-Defendants,	C.A. No. 05-00381 (KAJ)
v.	**JURY TRIAL DEMANDED**
BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.,	
Defendants/Counterclaim-Plaintiffs.	

DEFENDANTS BARR LABORATORIES, INC.'S AND BARR PHARMACEUTICALS, INC.'S OBJECTIONS AND ANSWERS TO PLAINTIFFS' FIRST SET OF INTERROGATORIES (Nos. 1-3)

Defendants/Counterclaim-Plaintiffs Barr Laboratories, Inc., and Barr Pharmaceuticals, Inc., (collectively, "Barr") by and through the undersigned attorneys and pursuant to Federal Rules of Civil Procedure 26 and 33, submit their Objections and Answers to Plaintiffs/Counterclaim-Defendants Janssen Pharmaceutica N.V.'s, Janssen, L.P.'s and Synaptech, Inc.'s (collectively, "Plaintiffs") First Set of Interrogatories (Nos. 1-3). These Objections and Answers are based on information and documents presently available as a result of a search and review process that is continuing. Barr reserves the right to supplement and/or amend their answers as necessary or appropriate.

OBJECTIONS APPLICABLE TO ALL INTERROGATORIES

1. Barr objects to Plaintiffs' interrogatories to the extent that they:

(a) Seek information that is not relevant to any claim or defense raised

in this litigation, and are not reasonably calculated to lead to the discovery of relevant, admissible evidence;

(b) Seek information that is not in the possession, custody, or control of Barr;

(c) Seek information already known to Plaintiffs or available to Plaintiffs from documents in their own files, from public sources, or from the documents that have been produced in this case;

(d) Seek information subject to a confidentiality obligation of a nonparty to this lawsuit without prior consent of that nonparty;

(e) Seek information that is unreasonably cumulative or duplicative of other requests, or are obtainable from some other source that is more convenient, less burdensome, or less expensive;

(f) Seek production in this action of trade secrets or other confidential information before a protective order is entered by the Court;

(g) Seek information for which the burden or expense of production outweighs its likely benefit in resolving the issues of this action;

(h) Seek to impose discovery obligations upon Barr beyond those provided for by the Federal Rules of Civil Procedure and/or the Local Rules of this Court.

Barr objects to Plaintiffs' Interrogatories, including but not limited to the Definitions and Instructions, to the extent that they call upon Barr to disclose information protected from discovery because of the attorney-client privilege and/or the attorney work product doctrine, or because they otherwise call upon Barr to disclose the mental impressions, conclusions, considerations, opinions, or legal theories of attorneys or other representatives of Barr concerning this lawsuit. Any inadvertent production shall not be deemed a waiver of any

privilege with respect to such information or of any work product doctrine which may apply. Moreover, Barr objects to Plaintiffs' Interrogatories to the extent that they purport to request information and/or documents generated or dated after the filing of the lawsuit herein. Such information and documents will not be provided absent some agreement with Plaintiffs concerning what relevant and admissible documents, if any, are needed that would be dated after the filing date of the Complaint. Additionally, Barr does not intend to prepare a privilege log for any information or documents generated after the filing date of Plaintiffs' Complaint against Barr because doing so would be too burdensome given the active and ongoing involvement of attorneys. Plaintiffs should advise Barr if they object to this limitation.

2. Barr's investigation and discovery regarding facts relevant to this case are ongoing. Barr expressly reserves the right to supplement and/or amend these responses when their discovery and investigations are complete.

3. Barr objects to Plaintiffs' definition of the term "the '318 patent" as overly broad and not reasonably calculated to lead to the discovery of relevant, admissible evidence. Unless otherwise stated, for purposes of Barr's discovery responses, "the '318 patent" shall refer solely to U.S. Patent No. 4,663,318, issued on May 5, 1987, and *not* to "any foreign counterpart" of that patent.

4. Barr objects to those interrogatories which request the identity of "every person with knowledge" or include comparable requests, on the grounds that such requests are overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to these objections and as set forth in response to each interrogatory where applicable, Barr will identify those individuals who are the most knowledgeable or who have primary responsibility for the information requested.

SPECIFIC OBJECTIONS AND ANSWERS TO INTERROGATORIES

Interrogatory No. 1

Separately for each claim and each product, if you contend that any drug product containing galantamine or any salt thereof for which you are seeking FDA approval does not infringe any claim of the '318 patent, describe the basis for that contention.

ANSWER:

Barr, in addition to their general objections, objects to this Interrogatory on the grounds that it is overly broad, unduly burdensome and seeks information not reasonably calculated to lead to the discovery of relevant, admissible evidence in that it seeks information regarding "any drug product containing galantamine or any salt thereof" when the only drug product at issue is the drug product that is the subject of Barr's ANDA No. 77-605, which is the subject of Plaintiffs' Complaint against Barr.

This Interrogatory also is overly broad because among other things, this Interrogatory seeks a response with respect to claims of the patent-in-suit that Plaintiffs have not identified are or would be infringed by the products that are the subject of Barr's ANDA No. 77-605 or by the manufacture, use, sale or offer for sale of the products that are the subject of Barr's ANDA No. 77-605. For example, Plaintiffs, despite repeated requests, refuse to specify which claims of the '318 patent allegedly are infringed by the products that are the subject of Barr's ANDA No. 77-605, and to provide, among other things, their claim construction of the asserted claims of the '318 patent. Plaintiffs have failed to identify these claims despite having received Barr's entire ANDA No. 77-605 on approximately June 4, 2005, and using that information to file their Complaint against Barr. Plaintiffs refusal to identify the claims that they are asserting against Barr is an unreasonable position given that under Rule 11 of the Federal Rules of Civil

Procedure, Plaintiffs must know what claims of the '318 patent they contend that Barr's ANDA products infringe or otherwise they are in violation of Rule 11.

Further, until such time as Plaintiffs identify which patent claims that they are asserting against Barr and what those claims mean, Barr objects to this Interrogatory as premature. Once Plaintiffs identify which claims of the '318 patent that they are asserting against Barr and provide their construction of these claims in response to Interrogatory No. 2 of Barr's First Set of Interrogatories served on September 15, 2005, Barr will supplement their answer to this Interrogatory with respect to the asserted claims of the '318 patent.

Barr further objects to the extent that this Interrogatory seeks to invade the attorney-client privilege or the work product doctrine.

Interrogatory No. 2

Separately for each claim, if you contend that any claim of the '318 patent is invalid for failure to comply with one or more of the provisions for patentability found in the U.S. Code, describe the basis for that contention.

ANSWER:

Barr, in addition to their general objections, objects to this Interrogatory on the grounds that it is overly broad and seeks information not reasonably calculated to lead to the discovery of relevant, admissible evidence. Among other things, this Interrogatory seeks a response with respect to claims of the patent-in-suit that Plaintiffs have not asserted are or would be infringed by the products that are the subject of Barr's ANDA No. 77-605 or by the manufacture, use, sale or offer for sale of the products in Barr's ANDA No. 77-605. Plaintiffs have failed to identify these claims despite having received Barr's entire ANDA No. 77-605 on approximately June 4, 2005 and using that information to file their Complaint against Barr. Plaintiffs' refusal to identify the claims that they are asserting against Barr is an unreasonable

position given that under Rule 11 of the Federal Rules of Civil Procedure, Plaintiffs must know what claims of the '318 patent they contend that Barr's ANDA products infringe or otherwise they are in violation of Rule 11. Until such time as Plaintiffs identify which patent claims that they are asserting and what those claims mean, Barr objects to this Interrogatory as premature. Once Plaintiffs identify which claims of the '318 patent that they are asserting and provide their construction of these claims in response to Interrogatory No. 2 of Barr's First Set of Interrogatories served on September 15, 2005, Barr will supplement their answer to this Interrogatory with respect to the '318 patent. Barr further objects to the extent this Interrogatory seeks to invade the attorney-client privilege or the work product doctrine.

Without waiving their objections, and subject to them, Barr responds that claims 1-7 of the '318 patent are invalid for obviousness under 35 U.S.C. § 103(a) in view of at least the following prior art references:

- Rathmann, K.L. and Conner, C.S., "Alzheimer's Disease: Clinical Features, Pathogenesis, and Treatment," *Drug Intell. Clin. Pharm. 18:684-91* (1984)
- Cozanitis, D.A., "L'hydrobromide de galanthamine: un substitut du sulfate d'eserine (physostigmine) pour le traitement des effects cerebraux des substances anti-cholinergiques," *Nouv. Presse Med. 34:4152* (1978)

The patentee did not cite, and the U.S. Patent and Trademark Examiner did not consider, any of these references, all of which were publicly available prior to January 15, 1998, and therefore constitute prior art under 35 U.S.C. § 102(b).

Barr reserves its rights, *inter alia*, to amend and/or supplement this response once Plaintiffs identify and construe the asserted claims of the '318 patent; to amend and/or supplement this response as discovery progresses in this litigation; and to rely on other prior art references identified by any other Defendant in any of the related actions filed by

Plaintiffs in connection with galantamine hydrobromide in support of Barr's invalidity claims.

Interrogatory No. 3

Identify each witness you expect to call at trial.

ANSWER:

Barr objects to this Interrogatory on the grounds that it is premature. Barr further objects to the extent that this Interrogatory seeks to invade the attorney-client privilege and/or the attorney work product doctrine. Without waiving their objections, and subject to them, Barr states that to the extent that they have so far identified any persons that they expect to call at trial as fact witnesses, such witnesses have been identified in Barr's Rule 26(a)(1) Disclosures, served on October 10, 2005. Barr further states that, they will provide their list of anticipated witnesses to Plaintiffs on a date directed by the Court or at least 30 days before trial, as required under Federal Rule of Civil Procedure 26(a)(3).

Date: October 11, 2005

BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.

By: Brian E. Farnan

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Attorneys for Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

The undersigned attorney certifies that he caused a copy of the foregoing Barr Laboratories, Inc.'s And Barr Pharmaceuticals, Inc.'s Objections And Answers To Plaintiffs' First Set Of Interrogatories (Nos. 1-3) to be served by hand on the 11th day of October, 2005 upon:

Steven J. Balick
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P.O. Box 1150
Wilmington, DE 19801

and by Federal Express for delivery on the 11th day of October, 2005 upon

George F. Pappas
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1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Brian E. Farnan

Exhibit C

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

- - -

IN RE: '318 PATENT INFRINGEMENT LITIGATION, : CIVIL ACTION : NO. 05-356 (KAJ) : (Consolidated)

- - -

Wilmington, Delaware
Tuesday, December 20, 2005 at 10:00 o'clock, a.m.
TELEPHONE SCHEDULING CONFERENCE

- - -

BEFORE: HONORABLE KENT A. JORDAN, U.S.D.C.J.

- - -

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and Par Pharmaceutical Companies, Inc.

- oOo -

P R O C E E D I N G S

(REPORTER'S NOTE: The following scheduling conference was held in chambers, beginning at 10:00 a.m.)

THE COURT: Hi, this is Judge Jordan. I need to have whoever is on the line please introduce yourselves and name the party you represent.

MR. BALICK: Your Honor, good morning. For the plaintiff, Steve Balick locally; and also on the line from the Covington & Burling firm are George Pappas, Christopher Sipes and Laura McNeill; and from Johnson & Johnson, Steven Berman.

THE COURT: Okay.

MR. MATTERER: Good morning, Your Honor. This is Mary Matterer from Morris James representing Mylan; and we have also on the line Christine Siwik from the Rakoczy

say, Mr. Pappas, you never really figured there would be much of an infringement case anyway. But we started with a two-week trial. Now we have a stipulation regarding the accused products falling within or the ANDA falling within the scope of the claims and I'm still at a two-week trial based on the parties submission. And that's okay.

I'm leaving it on for two weeks, but I am moving this trial up. I'm going to move this trial up by a few months because I don't want -- and I'm starting to get the sense that part of the Court's scheduling mechanism might be being used in a bigger business sense. And that is, I'm not saying it's happening. I just get concerned about that. And it should not take as long to get this case ready for trial now.

So I'm moving this case up to June. I've got time to do it in June of '07 and I'm going to do it in June of '07. It's not as early as the defendants want but it's several months sooner in the game. And I'm not unsympathetic to the pressure that the impending change in the patent status has on the business planning. So I'm mindful of it and I'm making a shift.

And to the extent that there are problems with third-party discovery which were alluded to in Mr. Balick's letter, I just want to say, please, if you think you are going to need third-party discovery overseas -- this goes

for plaintiff and any of the defendants -- don't wait to do it. Here is a statement that plaintiffs may need to need the formal exchange of informal discovery. If that is true, I urge you to move forward on that as soon as possible so that if formal channels have to be dealt with instead of informal channels, we're not down the road months with a statement that we thought we could work it out and then it turned out we couldn't and now we have to go through the Hague Convention and now please extend discovery. That would be I think a mistaken way to approach it. It's better to have the formal processes working and then if something informal can be worked out, great.

Likewise, the assertions about discovery disputes which were in this letter, if you folks have discovery disputes and you can't work them out, bring them on. Give me a call. We'll set a time, we'll get things worked out. I would much prefer not to have discovery disputes at all, obviously, but I would rather deal with discovery disputes than not know about them and then months later here, now we need an extension in the schedule because we couldn't get cooperation.

So I expect all sides to cooperate reasonably. I'm not asking the defense to respond to the assertions made in the December 19th letter, but if it's in fact the case that you've been asked to produce all documents related to

Exhibit D

REDACTED

Exhibit E

REDACTED

Exhibit F

REDACTED

Exhibit G

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT LITIGATION	:	Civil Action No. 05-356 (KAJ) (Consolidated)

DEFENDANTS BARR PHARMACEUTICALS, INC.'S AND BARR LABORATORIES INC.'S SUPPLEMENTAL OBJECTIONS AND RESPONSE TO PLAINTIFFS' INTERROGATORY NO. 2

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Defendants Barr Pharmaceuticals, Inc. and Barr Laboratories, Inc. (collectively "Barr") supplement their response to Plaintiffs' Interrogatory No. 2. Barr reserves the right to supplement or amend its objections and response as it obtains additional information during the course of discovery.

GENERAL OBJECTIONS

The following general objections to Plaintiffs' Interrogatories (including Definitions and Instructions) are hereby incorporated into Barr's supplemental objections and response to Plaintiffs' Interrogatory No. 2 as if fully set forth therein.

1. Barr objects to Plaintiffs' Interrogatories to the extent they call for responses that would require disclosure of information that is protected by the attorney-client privilege, the attorney work-product doctrine, or any other evidentiary privilege.

2. Barr objects to Plaintiffs' Interrogatories (including Definitions and Instructions) to the extent that they purport to impose discovery obligations beyond those required under the Federal Rules of Civil Procedure, the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, and any applicable Orders of the Court or agreements between counsel. Barr will follow the governing rules, orders, and agreements in

responding to these Interrogatories. Barr particularly objects to the Definitions and Instructions on these grounds to the extent that they call for response obligations beyond those required by Federal Rule of Civil Procedure 26(b)(1).

3. Barr objects to Plaintiffs' Interrogatories to the extent they are overly broad, unduly burdensome, and/or not reasonably calculated to lead to the discovery of admissible evidence.

4. Barr objects to Plaintiffs' Interrogatories to the extent an Interrogatory, or any words or terms used therein, is vague, ambiguous, subject to different interpretations, requires subjective knowledge by any party other than Barr, or involves issues of law subject to resolution by the Court. Barr will answer to the extent possible based on the most objectively reasonable interpretation of the Interrogatory.

5. Barr objects to Plaintiffs' Interrogatories to the extent they seek information beyond the possession, custody, or control of Barr, or to the extent the information requested is as readily available to Plaintiffs (or more so) as it is available to Barr.

6. Barr objects to Plaintiffs' Interrogatories to the extent they seek confidential or proprietary information of a non-party or seek highly confidential business or technical information that is of little or no relevance to the claims or defenses in this action.

7. Barr objects to Plaintiffs' Interrogatories to the extent that they are premature and Barr reserves the right to supplement its response pursuant to Federal Rule of Civil Procedure 26(e).

8. Barr objects to Plaintiffs' Interrogatories, including the Definitions and Instructions, to the extent they purport to define words or phrases in a manner different than their ordinary use, and Barr's response to such Interrogatories shall not be construed as an admission, agreement, or acquiescence in such a definition.

9. Barr objects to the definition of "you", "yours", and "Barr", and to those Interrogatories that incorporate these terms, to the extent that such terms are purported to include "all of Barr Pharmaceuticals, Inc.'s and Barr Laboratories, Inc.'s corporate parents, corporate predecessors and past or present subsidiaries, affiliates, divisions, departments, officers, directors, principals, agents and employees," or other non-parties to this case.

10. Barr objects to the definition of "Document" and to those Interrogatories that incorporate the term to the extent that Plaintiffs' definition of such term differs from the meaning or exceeds the scope of the usage of the term in Federal Rule of Civil Procedure 34(a).

11. Barr objects to the definition of "the '318 patent" and to those Interrogatories that incorporate the term to the extent that such term is purported to include "any foreign counterpart" to U.S. Patent No. 4,663,318 or any patents other than the patent asserted by Plaintiffs in the Complaint (*i.e.*, U.S. Patent No. 4,663,318).

12. Barr objects to the numbering of the Interrogatories to the extent that particular interrogatories include discrete subparts that are not separately numbered. To the extent that the total number of interrogatories, including discrete subparts, exceeds the permitted number set forth in the Federal Rules of Civil Procedure, Barr reserves the right to refuse to answer all Interrogatories in excess of that number should the parties be unable to come to an agreement on the issue.

BARR'S SPECIFIC OBJECTIONS AND RESPONSE

INTERROGATORY NO. 2:

Separately for each claim, if you contend that any claim of the '318 patent is invalid for failure to comply with one or more of the provisions for patentability found in the U.S. Code, describe the basis for that contention.

RESPONSE:

Barr objects to this Interrogatory to the extent it seeks information relating to any claims other than claims 1 and 4 of the '318 patent, in light of the December 2, 2005 Stipulation Not to Contest Infringement. (*See* 12/2/2005 Stipulation, ¶ 4.) Barr objects to this Interrogatory to the extent this contention interrogatory is premature and may call for expert testimony. *See, e.g.*, Fed. R. Civ. P. 26(a)(2)(C). Barr objects to this Interrogatory as improperly being characterized as one interrogatory because its multiple subparts constitute separate interrogatories toward the presumptive 25 interrogatory limit. *See* Fed. R. Civ. P. 33(a). Barr notes that the Court has not yet construed any claim terms, phrases, or clauses of the asserted claims nor have Plaintiffs provided Barr with Plaintiffs' contentions as to the proper construction of any disputed claim terms, phrases, or clauses. Claim construction, which is an issue for the Court, is the first step in an infringement and/or invalidity analysis. Barr reserves the right to supplement this response on this basis and on the basis of any additional discovery consistent with the Federal Rules of Civil Procedure, the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, and any relevant Orders of the Court. Barr further reserves the right to supplement its response to the extent that Plaintiffs change or otherwise supplement their contentions.

Subject to its general and specific objections, Barr responds to this Interrogatory as follows: Claim 1 of the '318 patent is directed to a "method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof." ('318 patent, claim 1.) Claim 1 is invalid under 35 U.S.C. § 102(b) as anticipated by at least P.A. Bhasker, *Medical Management of Dementia*, THE ANTISEPTIC, 71(1): 45-47 (1974) ("the Bhasker Article"). The Bhasker Article teaches treating "irreversible," "progressive

dementia," characterized by "a progressive fall-out of neurons and the course of the illness is rapidly downhill," with "small daily doses" of "Gallanthamine." One of ordinary skill in the art at the time of the invention would have understood the type of dementia described in the Bhasker Article to be or include at least Alzheimer's disease and/or related dementias. *See, e.g.*, K.L. Rathmann *et al.*, *Alzheimer's Disease: Clinical Features, Pathogenesis, and Treatment*, DRUG INTELL. CLIN. PHARM., 18: 684-91 (1984) ("the Rathmann Article") (teaches at least that Alzheimer's disease is a type of dementia); MERCK MANUAL (14th ed. 1982) (SYN RAZ 0006579-0006582) (teaches at least that Alzheimer's disease is a type of dementia "with a large loss of cells from the cerebral cortex and other brain areas," and that Alzheimer's dementia "progresses steadily."). One of ordinary skill in the art at the time of the invention would also have understood the Bhasker Article's "small daily doses" to be or include a "therapeutically effective amount." To the extent Plaintiffs contend any limitation of claim 1 of the '318 patent is not satisfied (and Plaintiffs have not to date), the claimed subject matter would have been obvious to one of ordinary skill in the art at the time of the invention in light of the Bhasker article alone, or in light of prior art articles or knowledge in the field as described further below.

Claim 4 of the '318 patent includes all of the limitations of claim 1 and further includes the limitations of "oral administration" in the range of "10–2000 mg per day." ('318 patent, claim 4.) Dosages within this range are a matter of routine experimentation and oral administration of galantamine[1] was well known. For example, claim 4 of the '318 patent is invalid as obvious, under 35 U.S.C. § 103 in view of the combination of the Bhasker Article and at least one of: D. Daskalov *et al.*, *Nivalin. Application and Rehabilitation Treatment of Cerebral Diseases with Aphasic Syndromes*, MBI MEDICO-BIOLOGIC INFORMATION, 3: 9-11

(1980) ("the Daskalov Article") (teaches at least oral administration of daily dosages of galantamine to humans in dosages including 10 mg, 15 mg, and 20 mg daily); and the Rathmann Article (teaches at least oral administration of daily doses of acetylcholinesterase inhibitors—a class of drugs including galantamine—to humans for treatment of Alzheimer's disease, and specifically administration of the acetylcholinesterase inhibitor physostigmine in dosages including 12–15 mg daily). The Bhasker article alone or in combination with at least one of the Daskalov Article and the Rathmann Article renders claim 4 invalid as obvious under 35 U.S.C. § 103 because one of ordinary skill in the art would have required only routine experimentation to determine dosages within the range of "10-2000 mg per day" of galantamine of claim 4, particularly in light of the extensive knowledge about galantamine's use in humans. In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to orally administer galantamine, as required by claim 4, and shown by the Daskalov Article.

Claims 1 and 4 of the '318 patent are also invalid as obvious under 35 U.S.C. § 103 in view of the combination of any two or more of: R.C. Mohs *et al.*, *Intravenous and Oral Physostigmine in Alzheimer's Disease*, INTERDISCIPL. TOPICS GERONT., 20: 150-152 (1985) (teaches at least administration of oral dosages of acetylcholinesterase inhibitors—specifically physostigmine—to humans for treatment of Alzheimer's disease in dosages including 12–24 mg per day); K.G. Pernov, *Nivalin and its Curative Effect upon Diseases of the Nervous System*, PSYCHIATRY AND NEUROLOGY AND MEDICAL PSYCHOLOGY BULLETIN ON RESEARCH AND PRACTICE, 13(11): 416-20 (1961) (teaches at least that galantamine hydrobromide and physostigmine—both acetylcholinesterase inhibitors—are chemically similar (*i.e.*, both are tertiary amines)); D.A. Cozanitis, *L'hydrobromide de Galanthamine: Unsubstitut du Sulfate*

[1] The terms galantamine and galanthamine are used interchangeably in the art.

D'eserine (Physostigmine) pour le Traitement des Effets Cerebraux des Substances Anti-Cholinergiques, NOUV. PRESSE MED., 7(45): 4152 (1978) (teaches at least that "galantamine hydrobromide . . . can have certain advantages over [physostigmine], due to its prolonged action," and that galantamine hydrobromide is able to cross the blood-brain barrier); UK Patent No. 942,200 (published 1963) (teaches at least that galantamine hydrobromide is "a strong anticholinesterase substance having an activity similar to that of [physostigmine], but showing a much less toxicity and a larger therapeutic range," and that galantamine hydrobromide acts on the central nervous system); B.S. Greenwald *et al.*, *Experimental Pharmacology of Alzheimer's Disease*, THE DEMENTIAS, 87-102 (teaches at least that "[i]n every study in which multiple doses of a cholinomimetic agent have been administered to patients with AD, a positive effect of the drug has been noted," and that physostigmine's "relatively short duration of action renders it less desirable therapeutically in the long-term treatment on nonfluctuating clinical conditions, such as [Alzheimer's disease]") the Daskalov Article (teaches at least oral administration of daily dosages of galantamine to humans in dosages including 10 mg, 15 mg, and 20 mg daily); and the Rathmann Article (teaches at least oral administration of daily doses of acetylcholinesterase inhibitors—a class of drugs including galantamine—to humans in for the treatment of Alzheimer's disease, and specifically administration of the acetylcholinesterase inhibitor physostigmine in dosages including 12–15 mg daily).

Regarding claim 1 of the '318 patent, these prior art articles teach the use of acetylcholinesterase inhibitors—a class of drugs that includes physostigmine and galantamine—and physostigmine specifically, to treat Alzheimer's disease; that physostigmine has some drawbacks for treatment of Alzheimer's disease, including a relatively short duration of action; that galantamine hydrobromide and physostigmine are chemically similar (*i.e.*, both are tertiary amines); that galantamine hydrobromide is a strong anticholinesterase substance having an

activity similar to that of physostigmine and can have certain advantages over physostigmine, including prolonged action, less toxicity, and a larger therapeutic range; and that galantamine, like physostigmine, was known to cross the blood-brain barrier. Consequently, it would have been obvious to one of ordinary skill in the art at the time of the invention to use galantamine to treat Alzheimer's disease and related dementias.

With respect to claim 4 of the '318 patent, these prior art articles additionally teach oral administration of both physostigmine and galantamine, and oral dosage ranges for both physostigmine and galantamine that fall within the claimed range of "10–2000 mg per day." Therefore, the claimed range of "10–2000 mg per day" of galantamine would have been obvious to one of ordinary skill in the art at the time of the invention. Additionally and/or alternatively, claim 4 is invalid as obvious under 35 U.S.C. § 103 because one of ordinary skill in the art at the time of the invention would have required only routine experimentation to determine dosages within the range of "10-2000 mg per day" of galantamine, as required by claim 4. Additionally, it is taught in the prior art and it would have been obvious to one of ordinary skill in the art at the time of the invention to orally administer galantamine, as required by claim 4.

Other prior art provides further support for Barr's contention that the '318 patent is invalid as being either anticipated under 35 U.S.C. § 102 (art reflecting knowledge in the field) or obvious under 35 U.S.C. § 103, including: A.R. Luria *et al.*, *Restoration of Higher Cortical Function Following Local Brain Damage*, DISORDERS OF HIGHER NERVOUS ACTIVITY, Ch. 21 (P.J. Vinken and G.W. Bruyn ed., North Holland Publishing Company 1969); B.S. Greenwald *et al.*, *Neurotransmitter Deficits in Alzheimer's Disease: Criteria for Significance*, J. AM. GERIATRICS SOC'Y, 31: 310-16 (1983); D.A. Cozanitis, *Galanthamine Hydrobromide, a Longer Acting Anticholinesterase Drug, in the Treatment of Central Effects of Scolpamine (Hyoscine)*, ANAESTHESIST, 26:649-50 (1977); L.J. Thal *et al.*, *Oral Physostigmine and Lecithin Improve*

Memory in Alzheimer Disease, ANNALS OF NEUROLOGY, 13:491-96 (1983); L.N. Nesterenko, *Influence Exerted by Galantamine on the Acetylcholinesterase Activity*, FARMAKOL TOKSIKOL, 28: 413-14 (1965); W. Göpel *et al.*, *Erfahrungen mit Nivalin in der Neurologischen Therapie*, PSYCHIAT. NEUROL. MED. PSYCHOL., 23: 712-18, (1971); C.M. Smith *et al.*, *Physostigmine in Alzheimer's Disease*, THE LANCET, 1: 42 (1979); R.C. Mohs *et al.*, *Clinical Studies of the Cholinergic Deficit in Alzheimer's Disease*, J. OF THE AM. GERIATRICS SOC'Y, 33(11): 749-57 (1985); R.C. Mohs *et al.*, *Oral Physostigmine Treatment of Patients With Alzheimer's Disease*, AM. J. OF PSYCHIATRY, 142(1): 28-33 (1985); V. Haroutunian *et al.*, *Cholinergic Modulation of Memory in Rats*, PSYCHOPHARMACOLOGY, 87(3): 266-71 (1985); K.L. Davis *et al.*, *Oral Physostigmine in Alzheimer's Disease*, PSYCHOPHARMACOLOGY BULLETIN, 19(3): 451-53 (1983); M.I. Levy *et al.*, *Research Subject Recruitment for Gerontological Studies of Pharmacological Agents*, NEUROBIOLOGY OF AGING, 3(1): 77-79 (1982); R. Yu. Il'yutchenok *et al.*, *Cholinergic Mechanisms of Memory: Analysis of the Amnesic Effect of Anticholinergic Drugs*, INT'L J. OF PSYCHOBIOLOGY, 2(3): 177-92 (1972); R. Yu. Il'yutchenok, *Pharmacological Aspects of Memory Neurochemical Regulation*, BULGARIAN ACADEMY OF SCIENCES: ACTA PHYSIOLOGICA ET PHARMACOLOGICA BULGARICA, 8(1-2): 43-49 (1982); V.A. Krauz *et al.*, *Role of Cholinergic Mechanisms in ATFase Activity and Glycolysis Intensity Regulation in the Rat Neocortex, Hippocampus and Truncus Cerebri*, FARMAKOLOGIA I TOKSIKOLOGIA, 1: 23-26 (1982); A. Plaitakis *et al.*, *Homer's Moly Identified As Galanthus Nivalis L.: Physiologic Antidote to Stramonium Poisoning*, CLINICAL NEUROPHARMACOLOGY, 6(1): 1-5 (1983); M. Bretagne *et al.*, *Essais Cliniques en Anesthesiologie D'un Nouvel Anticholinesterasique la Galanthamine*, ANESTHESIE ANALGESIE REANIMATION, 1: 285-92 (1965); G. Milbled *et al.*, *Sur L'action Centrale de la Galanthamine*, COMPETES RENDUS DES SEANCES DE LA SOCIETE DE BIOLOGIE ET DE SES FILIALES, 160(11): 2089-90 (1966); R. Yu. Il'yuchenok *et al.*, *Comparison*

of the Effects Produced By Anticholinergic and Anticholinesterase Substances on Induced Potential of the Cerebral Cortex, FARMAKOLOGIA I TOKSIKOLOGIA, Vol. 1 (1969); R. Yu. Il'yutchenok, *Cholinergic Brain Mechanisms and Behaviour*, PROGRESS IN BRAIN RESEARCH: ANTICHOLINERGIC DRUGS AND BRAIN FUNCTIONS IN ANIMALS AND MAN, 28: 134-48 (1968); D.A. Cozanitis *et al.*, *A Comparative Study of Galanthamine Hydrobromide and Atropine/Neostigmine in Conscious Volunteers*, THE ANAESTHESIST, 416-21 (1971); K.L. Davis *et al.*, *Physostigmine: Improvement of Long-Term Memory Processes in Normal Humans*, SCIENCE, 201(4352): 272-74 (1978); K.L. Davis *et al.*, *Enhancement of Memory Processes in Alzheimer's Disease with Multiple-Dose Intravenous Physostigmine*, THE AM. J. OF PSYCHIATRY, 139(11): 1421-24 (1982); B.H. Peters *et al.*, *Effects of Physostigmine and Lecithin on Memory in Alzheimer Disease*, ANNALS OF NEUROLOGY, 6(3): 219-21 (1979); and Von K.G. Pernov, *Das Nivalin und seine Heilwirkung bei Erkrankungen des Nervensystems*, PSYCHIATRIE NEUROLOGIE UND MEDIZINISCHE PSYCHOLOGIE, 13(11): 416-20 (1961). Barr further reserves its right to rely upon any additional prior art identified by Plaintiffs, Barr, and/or any other Defendant against whom the '318 patent is asserted.

With respect to the issue of obviousness, Plaintiffs have to date identified no evidence in support of any secondary considerations of non-obviousness that affect the obviousness of the claims.

To the extent Plaintiffs contend that claims 1 and/or 4 are not anticipated or rendered obvious by the prior art, the claims are invalid for failure to satisfy the enablement requirement under 35 U.S.C. § 112, ¶ 1. "[T]o satisfy the enablement requirement of section 112, an applicant must describe the manner of making and using the invention 'in such full, clear, concise and exact terms as to enable any person skilled in the art . . . to make and use the same . . . .'" *See Rasmusson v. SmithKline Beecham Corp*, 413 F.3d 1318, 1322 (Fed. Cir. 2005)

(quoting 35 U.S.C. § 112, ¶ 1). In the case of determining the utility of a drug or medicament, to enable an invention, an inventor has to do more than "merely propos[e] an unproved hypothesis." *Id.* at 1325. Mere plausibility is not enough. *See Id.* "If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to 'inventions' consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the 'inventor' would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis." *Id.* The '318 patent identifies no tests or studies in support of the claimed method of use, identifies no unknown property of the drug galantamine, and identifies no unknown scientific principle related to Alzheimer's or the effect of galantamine in the human body. "[W]here there is 'no indication that one skilled in the art would accept without question statements as to the effects of the claimed drug products and no evidence has been presented to demonstrate that the claimed products do have those effects,' an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement." *Id.* at 1323.

To the extent Plaintiffs contend Dr. Bonnie Davis invented anything not already known in the field, and therefore not anticipated under Section 102(b) nor obvious under Section 103, the '318 patent fails to provide an enabling disclosure and written description within the meaning of Section 112.

In addition, claim 4 is further invalid under 35 U.S.C. § 112, ¶ 1 because the inventor failed to teach one of ordinary skill in the art how to make or use the invention over the full scope of the recited range. Specifically, the specification does not teach one of ordinary skill that the entire recited range of "10-2000 mg per day" is a "therapeutically effective amount" as

required by claim 1. Therefore, claim 4 fails to provide both an enabling disclosure and an adequate written description under 35 U.S.C. § 112.

Respectfully submitted,

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Attorneys for Defendants/Counterclaim-Plaintiffs Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.

Dated: April 13, 2006

CERTIFICATE OF SERVICE

The undersigned attorney certifies that he caused two copies of the foregoing Defendants Barr Pharmaceuticals, Inc.'s and Barr Laboratories, Inc.'s Supplemental Objections and Response To Plaintiffs' Interrogatory No. 2 to be served by hand on the 13th day of April, 2006 upon:

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Exhibit H

REDACTED

Exhibit I

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March 2, 2007

VIA E-MAIL
Mr. Kurt G. Calia
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1201 Pennsylvania Ave., N.W.
Washington, D.C. 20004-2401

Re: In re '318 Patent Infringement Action

Dear Kurt:

I write regarding documents, including JAN RAZ 0011223-227 and SYN RAZ 0018373-74, produced by Plaintiffs in this case that show that a third-party, Dr. Michael Rainer, had the idea to use galantamine to treat Alzheimer's disease as early as October 1985, months before Dr. Bonnie Davis filed her patent application. Without explanation, Plaintiffs marked these documents Confidential under the Protective Order. We fail to see how these documents can be confidential when they contain information that is publicly available, including the use of cholinesterase inhibitors to treat Alzheimer's disease and Dr. Rainer's recommendation to use Nivalin (galantamine) to treat Alzheimer's disease. As you know, Dr. Rainer published on the use of galantamine to treat Alzheimer's disease and therefore any such information is not confidential. The Confidential designation is particularly objectionable because it precludes, for example, Dr. Rainer from reviewing his own work. It goes without saying that documents authored by Dr. Rainer cannot be confidential as to him.

Accordingly, Barr requests that Plaintiffs lift the Confidential designation on JAN RAZ 0011223-227 and SYN RAZ 0018373-74 (and any other similar documents). If Plaintiffs will not remove the Confidential designation as requested, Barr will seek the Court's assistance in resolving this issue.

As time is of the essence, I look forward to your response early next week.

Very truly yours,

Lynn M. Ulrich

LMU/dlg

Exhibit J

REDACTED